



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Seshi R. Sompuram and Halasya Ramanathan  
Application No.: 09/834,240 Group Art Unit: 1653  
Filed: April 12, 2001 Examiner: Robert B. Mondesi  
Confirmation No.: 5834  
Title: QUALITY CONTROL FOR CYTOCHEMICAL ASSAYS

CERTIFICATE OF MAILING OR TRANSMISSION	
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

03/09/2004 MAHME1 00000121 09834240

Sir:

02 FC:1806

180.00 OP

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☒ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed.
- ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. \_\_\_\_\_, to which priority under 35 U.S.C. §120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: March 3, 2004



PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 1159.1008-005		APPLICATION NO. 09/834,240	
<b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  March 3, 2004 (Use several sheets if necessary)				FIRST NAMED INVENTOR Seshi R. Sompuram	
				FILING DATE April 12, 2001	
EXAMINER Robert B. Mondesi				CONFIRMATION NO. 5834	GROUP 1653

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AV3	Capel, P.J.A., "The Defined Antigen Substrate Spheres (DASS) System and Some of its Applications," <i>Ann. NY Acad. Sci.</i> , 254:108-118 (1975).
AW3	Knapp, W., <i>et al.</i> , "Microfluorometry of Antigen - Antibody Interactions in Immuno fluorescence Using the Defined Antigen Substrate Spheres (DASS) System. Sensitivity, Specificity and Variables of the Method," <i>Journal of Immunological Methods</i> , 5:259-273 (1974).
AX3	Larsson, L-I, "A Novel Immunocytochemical Model System for Specificity and Sensitivity Screening of Antisera Against Multiple Antigens," <i>Journal of Histochemistry and Cytochemistry</i> , 29:408-401 (1981).
AY3	Millar, D.A., <i>et al.</i> , "A Step-Wedge Standard for the Quantification of Immunoperoxidase Techniques," <i>Histochemical Journal</i> , 14:609-620 (1982).
AZ3	Nairn, R.C., <i>et al.</i> , "Immunofluorescence in Cancer Investigation and Research," <i>Ann. NY Acad. Sci.</i> , 254:523-527 (1975).
AR4	Posthuma, G., <i>et al.</i> , "Usefulness of the Immunogold Technique in Quantitation of a Soluble Protein in Ultra-Thin Sections," <i>Journal of Histochemistry and Cytochemistry</i> , 35:405-410 (1987).
AS4	Streefkerk, J.G., <i>et al.</i> , "Agarose Beads as Matrices for Proteins in Cytophotometric Investigations of Immunohistoperoxidase Procedures," <i>Journal of Histochemistry and Cytochemistry</i> , 23:243-250 (1975).
AT4	Schnitt, S.J., <i>et al.</i> , "Current Status of HER2 Testing: Caught Between a Rock and a Hard Place," <i>Am. J. Clin. Pathol.</i> , 116:806-810 (2001).
AU4	Moskaluk, C.A., "Standardization of Clinical Immunohistochemistry: Why, How, and by Whom?," <i>Am. J. Clin. Pathol.</i> 118:669-671 (2002).
AV4	Wick, M.R., <i>et al.</i> , "Targeted Controls in Clinical Immunohistochemistry: A Useful Approach to Quality Assurance," <i>Am. J. Clin. Pathol.</i> 117:7-8 (2002).
AW4	Sompuram, S. R., <i>et al.</i> , "A Water-Stable Protected Isocyanate Glass Array Substrate," <i>Analytical Biochemistry</i> , 14 pages (2004).

EXAMINER	DATE CONSIDERED
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